

In re: Odidi et al.
Serial No. 09/845,497
Docket No. 9577-25

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The Claims:

1. (Currently Amended): An extended release pharmaceutical active formulation comprising:
 - **a capsule, tablet or pellet comprising** about 5-95% by weight pharmaceutical active ~~provided as a capsule, tablet or pellet;~~
 - ~~_____~~ **and** an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;
 - an encasement coat comprising one or more layers of a polymeric film encasing said **capsule, tablet or pellet pharmaceutical active**, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer of polyethylene glycol,
 - wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.
2. Cancelled
3. Cancelled
4. Cancelled
5. Cancelled
6. (Previously Amended): The formulation of claim 1, wherein said compression aid is present in an amount of up to about 60% by weight.
7. (Previously Amended): The formulation of claim 1, wherein said extrusion aid is present in an amount of up to about 50% by weight.
8. (Previously Amended): The formulation of claim 1, wherein said formulation additionally comprises excipients, lubricants, binders or glidants.

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9. (Previously Amended): The formulation of claim 1, wherein said polymeric film is a polymer selected from the group consisting of cellulose esters, polyvinyl acetate phthalate, methacrylic acid copolymers and any mixtures thereof.
10. Cancelled
11. (Original): The formulation of claim 1, wherein said polymeric film comprises shellac or zein.
12. Cancelled
13. Cancelled
14. Cancelled
15. (Previously Amended): The formulation of claim 1, wherein said pharmaceutical active is selected from the group consisting of risedronate, alendronate, riluzole, and sulfonylureas.
16. (Original): The formulation of claim 1, wherein said pharmaceutical active is selected from the group consisting of bioactive peptides, antitumor agents, antibiotics, antipyretic analgesic antiinflammatory agents, antitussive expectorants, sedatives, muscle relaxants, antiepileptics, antiulcer agents, antidepressants, anti-allergic agents, cardiotonics, antiarrhythmic agents, vasodilators, hypotensive diuretics, anticoagulants, hemolytics, antituberculosis agents, hormones, narcotic antagonists, bone resorption suppressors and angiogenesis suppressors.
17. (Previously Amended): An extended release pharmaceutical active formulation comprising:
- a capsule, tablet, pellet or bead of about 5-95% by weight pharmaceutical active, about 0-60% by weight pharmaceutical compression aid selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar, and about 0-50% by weight pharmaceutical extrusion aid.

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- an encasement coat comprising one or more layers of a polymeric film encasing said capsule, tablet, pellet or bead, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

- 18. Cancelled
- 19. Cancelled
- 20. Cancelled

21. (Previously Amended): The formulation of claim 17, wherein said polymeric film is a polymer selected from the group consisting of cellulose esters, polyvinyl acetate phthalate, methacrylic acid copolymers and any mixtures thereof.

22. (Original): The formulation of claim 15, wherein said polymeric film further comprises an agent selected from the group consisting of plasticizers, antitacking agents, colorants and mixtures thereof.

23. (Previously Amended): An extended release pharmaceutical active formulation comprising:

- a capsule, tablet, pellet or bead of pharmaceutical active comprising;
 - about 5-95% by weight pharmaceutical active;
 - about 0-60% by weight pharmaceutical compression aid;
 - about 0-50% by weight pharmaceutical extrusion aid; and
- an encasement coat comprising one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol,
 - wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

24. (Previously Amended): The formulation of claim 1, wherein greater than 80% of said

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pharmaceutical active is released in one hour when tested in a USP apparatus at 100 rpm in 900ml degassed water and 37°C.

25. (Previously Amended): The formulation of claim 1, wherein less than about 20% of the pharmaceutical active is released in one hour when tested in a USP apparatus at 75 rpm in 900ml simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and greater than 80% of the pharmaceutical active is released in one hour when tested in a USP apparatus at 75 rpm in 900ml simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C.

26. (Previously Amended): The formulation of claim 1, wherein the tablet or pellet is made by direct compression.

27. (Original): The formulation of claim 15, wherein the release of the pharmaceutical active exhibits a lag phase (time) and after which release is extended over 12 hours or 24 hours after administration.

28. (Previously Amended): The formulation of claim 1, wherein the capsule, tablet, pellet or bead demonstrates extended release characteristics of greater than 4 hours when tested in a USP apparatus at 100 rpm in 900ml degassed water and 37°C.

29. (Previously Amended): The formulation of claim 1, wherein said capsule, tablet, pellet or bead demonstrates extended release characteristics of greater than 4 hours when tested in a USP apparatus at 75 rpm in 900mls simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and demonstrates extended release characteristics of greater than 4 hours when tested in a USP apparatus at 75 rpm in 900mls simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C.

30. (Original): The formulation of claim 21, wherein pharmaceutical active release exhibits a lag phase (time) after which release is extended over 12 hours or 24 hours when administered to humans or animals in the presence of food.

31. (Previously Amended): A method for making an extended release pharmaceutical active formulation comprising:

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- compressing about 5-95% by weight pharmaceutical active into a capsule, tablet or pellet with an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

- encasing said tablets, pellets or beads in an encasement coat comprising one or more layers of a polymeric film, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer of polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

32. (Previously Amended): The method of claim 31, wherein said pharmaceutical compression aid is present in an amount of up to about 60% by weight and said pharmaceutical extrusion aid is present in an amount of up to about 50% by weight.

33. (Previously Amended): An extended release pharmaceutical active formulation comprising:

- a pharmaceutical active provided as a capsule, tablet or pellet comprising:

- about 5-95% by weight pharmaceutical active;

- about 0-60% by weight pharmaceutical compression aid selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

- about 0-50% by weight pharmaceutical extrusion aid; and

- an encasement coat comprising one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer.

34. (Previously Amended): The formulation of claim 1, wherein said pharmaceutical active is selected from the group consisting of glyburide, chlorpropamide, tolbutamide, glimepiride, acarbose, alglucerase, miglitol, nateglinide, plmagidine, ploglitazone,

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pramlintide, repaglinide, rosiglitazone, troglitazone, hypoglycemic benzenesulfonamido
pyrimidines, buformin and phenformin.